



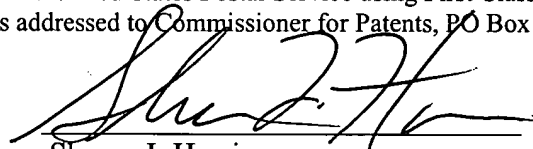
THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Boris P. Kovatchev, et al.	}	Customer No.	34444
Serial No.	10/524,094 ✓	}	Art Unit:	1652
Filed:	February 9, 2005	}	Examiner:	Unknown
Title:	Managing and Processing Self-Monitoring Blood Glucose			

Certificate of Mailing Under 37 CFR §1.8

I hereby certify that this correspondence is being deposited with the United States Postal Service using First Class Service under 37 C.F.R. § 1.8 on the date indicated below and is addressed to Commissioner for Patents, PO Box 1450, Alexandria, VA 22313-1450.

Date: July 17, 2006


Shawn J. Harris

**TRANSMITTAL OF INFORMATION DISCLOSURE STATEMENT
UNDER 37 C.F.R. 1.97 (b)(3)**

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Sir:

Submitted herewith please find an Information Disclosure Statement for the above identified application, consisting of Form PTO/SB/08A along with eight (8) copies of Foreign Patent documents, Form PTO/SB/08B, and copies of ninety-three (93) references. The Information Disclosure Statement is being filed before the mailing date of a first Office Action on the merits per 37 C.F.R. 1.97(b)(3).

Applicants respectfully submit that the filing of this Information Disclosure Statement is not a representation that a prior art search was conducted or that the information cited is material to the patentability of the invention as defined in 37 CFR § 1.56, or that any cited document is prior art. Applicants request that the Examiner consider the references, determine their relevance to the present application, if any, and list the references on the face of any patent

which may issue from the present application. Applicants further request that an initialed copy of Forms PTO/SB/08A and PTO/SB/08B be returned to applicants.

No fees are believed to be due for this submission. If this belief is in error, the Commissioner is hereby authorized to charge any fees due for this submission to Deposit Account No. 50-0423, as well as credit any refunds.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'R. Decker', with a long horizontal flourish extending to the right.

Robert J. Decker
Registration No. 44,056

July 17, 2006

University of Virginia Patent Foundation
250 West Main Street, Suite 300
Charlottesville, VA 22902
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PTO/SB/08A (10-96)

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet

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of

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Complete if Known

Application Number	10/524,094
Filing Date	2/9/2005
First Named Inventor	Boris P. Kovatchev, et al.
Group Art Unit	1652
Examiner Name	Unknown
Attorney Docket Number	00543-22

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code ² (if known)			
	1	6,027,692		GALEN, et al.	01-22-2000	Entire Document
	2	5,997,476		BROWN	07-12-1999	Entire Document
	3	5,971,922		ARITA, et al.	10-26-1999	Entire Document
	4	5,822,935		HIRAI, et al.	03-16-1999	Entire Document
	5	5,251,126		KAHN, et al.	03-10-1993	Entire Document
	6	5,206,144		ZEUTHEN, et al.	04-27-1993	Entire Document
	7	6,081,786		BARRY, et al.	06-27-2000	Entire Document
	8	6,188,988		BARRY, et al.	02-13-2001	Entire Document
	9	5,431,793		WANG, et al.	07-11-1995	Entire Document
	10	5,453,379		YAMAZAKI, et al.	09-26-1995	Entire Document
	11	6,054,039		SHIEH	04-25-2000	Entire Document
	12	6,175,752		SAY, et al.	01-15-2001	Entire Document
	13	5,741,211		RENIRIE, et al.	04-21-1998	Entire Document
	14	5,108,564		SZUMINSKI, et al.	04-28-1992	Entire Document
	15	5,128,015		SZUMINSKI, et al.	07-07-1992	Entire Document
	16	6,144,869		BERNER, et al.	11-07-2000	Entire Document
	17	5,801,057		SMART, et al.	09-01-1998	Entire Document
	18	4,731,726		ALLEN, III	03-15-1998	Entire Document
	19	6,272,480		TRESP, et al.	08-07-2001	Entire Document
	20	6,233,471		BERNER, et al.	05-15-2001	Entire Document

FOREIGN PATENT DOCUMENTS

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	21	5,019,974		BECKER	05-28-1991	Entire Document
	22	5,840,020		HEINONEN et al.	11-24-1998	Entire Document
	23	5,748,851		IOKIBE et al.	05-05-1998	Entire Document
	24	5,989,409		KURNIK et al.	11-23-1999	Entire Document
	25	5,558,638		EVERS et al.	09-24-1996	Entire Document
	26	5,267,152		YANG, et al.	11-30-1993	Entire Document
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	28	5,086,229		ROSENTHAL, et al.	02-04-1992	Entire Document
	29	4,975,581		ROBINSON, et al.	12-04-1990	Entire Document
	30	5,036,861		SEMBROWICH, et al.	08-06-1991	Entire Document
	31	5,076,273		SCHOENDORFER, et al.	12-31-1991	Entire Document
	32	5,140,985		SCHROEDER, et al.	08-25-1992	Entire Document
	33	5,279,543		GLIKFELD, et al.	01-19-1994	Entire Document
	34	5,822,715		WORTHINGTON, et al.	10-13-1998	Entire Document
	35	5,139,023		STANLEY, et al.	08-18-1992	Entire Document

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		Office ³	Number ⁴	Kind Code ⁵ (if known)				
	36	EP	0834825		SALZSIEDER, et al.	04-08-1998	Entire Document	
	37	WO	0018289		CYGNUS, INC.	04-06-2000	Entire Document	
	38	WO	0019888		Reagents of Univ of CA	04-13-2000	Entire Document	
	39	WO	9929230		E.HELLER & CO.	06-17-1999	Entire Document	
	40	WO	0018293		Health Hero Network LLC	04-06-2000	Entire Document	
	41	WO	9600110		CYGNUS, Inc.	01-04-1996	Entire Document	
	42	DE	20305978 U 1		DITTLER, Jan	07-24-2003	Entire Document	
	43	GB	2159625 A		KREBS, Peter Eric	12-04-1985	Entire Document	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 1 of 9

Complete if Known

Application Number 10/524,094
 Filing Date 2/9/2005
 First Named Inventor Boris P. Kovatchev, et al.
 Group Art Unit 1652
 Examiner Name Unknown
 Attorney Docket Number 00543-22

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS

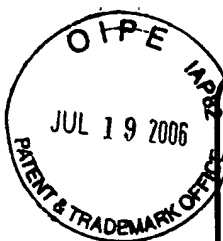
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	A	COX, et al.: "Frequency of Severe Hypoglycemia in Insulin-Dependent Diabetes Mellitus Can be Predicted from Self-Monitoring Blood Glucose..." J of Clinical End. and Met., Vol. 79, No. 6, pp 1659-1662. (1994)	
	B	KOVATCHEV, et al.: "Assessment of Risk for Severe Hypoglycemia Among Adults with IDDM", Diabetes Care, Vol. 21, No. 11, November (1998)	
	C	KOVATCHEV, et al.: "Symmetrization of the Blood Glucose Measurement Scale and its Applications", Diabetes Care, Vol 20, No. 11, November (1997)	
	D	KOVATCHEV, et al.: "Risk Analysis of Blood Glucose Data: A Quantitative Approach to Optimizing the Control of Insulin Dependent Diabetes", J. of Theoretical Medicine, pp 1 - 10, January (2000)	
	E	KOVATCHEV, et al.: "Episodes of Severe Hypoglycemia in IDDM are Preceded, and Followed, within 48 hours by Measurable Disturbances..."	
	F	KOVATCHEV, et al.: "Assoc. of Self-Monitoring Blood Glucose Profiles with Glycosylated Hemoglobin in Patients...", Methods in Enzymology, Vol 321, pp 410-417, (2000)	
	G	LEHMANN, E.D., et al.: "Computer assisted diabetes care: a 6-year retrospective", Computer Methods and Programs in Biomedicine, 50, 209-230 (1996)	
	H	DEUTSCH, T., et al.: "Time series analysis and control of blood glucose levels in diabetic patients", Computer Methods and Programs in Biomedicine, 41, 167-182 (1994)	
	I	LEHMANN, E.D., et al.: "AIDA: an interactive diabetes advisor", Computer Methods and Programs in Biomedicine, 41, 183-203, (1994)	
	J	LEHMANN, E.D., et al.: "Retrospective validation of physiological model of glucose-insulin interaction in type 1 diabetes mellitus", Med. Eng. Phys., Vol. 16, 193-202, May (1994)	
	K	LEHMANN, E.D., et al.: "Extended Conference Report: Computers in Diabetes '96", Med. Inform, Vol. 22, No. 1, 105-118, (1997)	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 2 of 9

Complete if Known

Application Number	10/524,094
Filing Date	2/9/2005
First Named Inventor	Boris P. Kovatchev, et al.
Group Art Unit	1652
Examiner Name	Unknown
Attorney Docket Number	00543-22

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	L	LEHMANN, E.D., et al.: "Application of computers in diabetes care -- a review. I. Computers for data collection and interpretation", Vol. 20, No. 4, 281-302, (1995)	
	M	DEUTSCH, T. et al.: "UTOPIA: a consultation system for visit-by-visit diabetes management", Med Inform, Vol. 21, No. 4, 345-358 (1996)	
	N	LEHMANN, E.D., et al.: "Compartmental models for glycaemic prediction and decision-support in clinical diabetes care: promise and reality" Computer Methods and Programs in Biomedicine, Vol. 56, 193-204, (1998)	
	O	LEHMANN, E.D., et al.: "A physiological model of glucose--insulin interaction in type 1 diabetes mellitus", J. of Biomedical Engineering Vol. 14, No. 3, 235-242 (1992)	
	P	TRAJANOSKI, ZLATKO, et al.: "Simulation studies on neural predictive control of glucose using the subcutaneous route", Comp Methods and Programs in Biomed., Vol. 56, Iss 2, 133-139, May (1998)	
	Q	TRAJANOSKI, ZLATKO, et al.: "Fuzzy filter for state estimation of a glucoregulatory system", Comp. Methods and Programs in Biomedicine, Vol. 50, 265-273, (1996)	
	R	TRAJANOSKI, ZLATKO, et al.: "Regularization networks for Glucose System Identification", Institute of Biomedical Engineering, 1083-, 0-7803-2050-6/94 ABSTRACT ONLY	
	S	REGITTNIG, W. et al.: "Glucose-mediated glucose disappearance during the intravenous...", 18th Annual International Conference of the IEEE Eng. in Medicine and Biology Society, Amsterdam, 0-7803-3811-1/97	
	T	FISCHER, UWE, et al.: "Experimental validation of a glucose- insulin control model to simulate patterns in glucose turnover", Comp. Methods and Programs in Biomedicine, Vol. 32, 249-258 (1990)	
	U	SALZSIEDER, E., et al.: "A Model-based System for the Individual Prediction of Metabolic Responses to Improve Therapy in Type 1 Diabetes", Central Inst. of Diabetes, Horm. Metab. Res, 24 (Suppl) 10-19 (1990)	
	V	SALZSIEDER, ECKHARD, et al.: "Computer-aided systems in the management of type I diabetes: the application of a model-based strategy", Computer Methods and Programs in Biomedicine, Vol. 32, 215-224, (1990)	

Examiner
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 3 of 9

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Application Number	10/524,094
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First Named Inventor	Boris P. Kovatchev, et al.
Group Art Unit	1652
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OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS

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	W	SALZSIEDER, ECKHARD, et al.: "Model-Based Prevention in IDDM of Exercise-Induced Hypoglycemia", ABSTRACT ONLY	
	X	BLECKERT, GABRIELE, et al.: "Mixed graphical models for simultaneous model identification and control applied to the glucose-insulin metabolism", Computer Method and Programs in Biomed Vol. 56, 141-155 (1998)	
	Y	MARTIN, IVA K, et al.: "Application of the SAAM modeling program to minimal model analysis of intravenous glucose tolerance test data", Computer Methods and Programs in Biomedicine, Vol. 33 193-203(1990)	
	Z	WARD, G. M., et al.: "Physiologic Modeling of the Intravenous Glucose Tolerance Test in Type 2 Diabetes: A new Approach to the Insulin Compartment", Metabolism, Vol 50, No. 5, 512-519, May (2001)	
	AA	WARD, G. M., et al.: "A Modified Minimal Model Analysis of Insulin Sensitivity and Glucose-Mediated Glucose Disposal in Insulin-Dependent Diabetes", Metabolism, Vol. 40, No. 1, 4-9, January (1991)	
	BB	THOMASETH, KARL, et al.: "Parameter Information Content During Model Identification Experiments", 3rd IFAC Symposium on Modelling and Control in Biomedical Systems, Warwick UK, 107-112 (1997)	
	CC	PACINI, GIOVANNI, et al.: "Estimation of B-cell Secretion and insulin hepatic extraction by the minimal modelling technique", Computer Methods and Programs in Biomedicine, Vol. 32, 241-248, (1990)	
	DD	BELLAZZI, R., et al.: "Bayesian Analysis of Blood Glucose Time Series from Diabetes Home Monitoring", IEEE Transactions on Biomedical Engineering, Vol. 47, No. 7, 971-, July (2000)	
	EE	BELLAZZI, R, et al.: "The Subcutaneous Route to Insulin-Dependent Diabetes Therapy", IEEE Engineering in Med. and Bio., Vol. 20, No. 1, 54-64, Jan (2001)	
	FF	RIVA, A., et al.: "High Level Control Strategies for Diabetes Therapy", Proceedings of the Fifth Conference on Artificial Intelligence in Medicine Europe, No. 934 in Lecture Notes in Artificial Intelligence, p 185-196, (1995)	
	GG	ARLETH, T. et al.: "A model of the edogenous glucose balance incorporating the characteristics of glucose transporters", Computer Methods and Programs in Biomedicine, Vol. 62, 219-234, (2000)	

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		Group Art Unit	1652
		Examiner Name	Unknown
Sheet 4 of 9	Attorney Docket Number	00543-22	

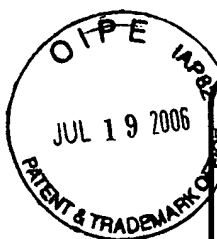
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	HH	STURIS, JEPPE, et al.: "Computer model for mechanisms underlying ultradian oscillations of insulin and glucose", Am. J. of Physiol., Modeling Methodology Forum, E801-E809, (1991)	
	II	QUON, MICHAEL, et al.: "Non-Insulin-Mediated Glucose Disappearance in Subjects with IDDM Discordance Between...", Diabetes, Vol. 43, 890-, July (1994)	
	JJ	MUZIC, R. et al.: "COMKAT: Compartment Model Kinetic Analysis Tool", The Journal of Nuclear Medicine, Vol. 42, No. 4, April (2001)	
	KK	FREELAND, ANGELA, et al.: "Inference of Blood Glucose Concentrations from Subcutaneous Glucose...", Annals of Biomedical Engineering, Vol. 27, 525-537, (1999)	
	LL	BERGER, MARCUS, et al.: "Computer Simulation of Plasma Insulin and Glucose Dynamics After Subcutaneous Insulin Injection", Diabetes Care, Vol. 12, No. 10, November (1989)	
	MM	FINEGOOD, D., et al.: "Reduced glucose effectiveness associated with reduced insulin release: an artifact of the minimal-model method", Am. J. of Physiol. Endocrin. Metab. 271, E485-E495, (1996)	
	NN	NAYLOR, J. S., et al.: "Comparison of parametrized models for computer-based estimation of diabetic patient glucose response", Med. Inform., Vol. 22, No. 1, 21-34, (1997)	
	OO	ANDREASSEN, S.: "Model-Based Biosignal Interpretation", Meth Inform Med, Vol. 33, 103-110, (1994)	
	PP	WORTHINGTON, D.: "The use of models in the self-management of insulin-dependent diabetes mellitus", Computer Methods and Programs in Biomedicine, Vol. 32, 233-239, (1990)	
	QQ	CARSON, E.R.: "Information technology and computer-based decision support in diabetic management", Computer Methods and Programs in Biomedicine, Vol. 32, 179-188, (1990)	
	RR	GOMEZ, E.J, et al.: "Telemedicine for diabetes care: the DIABTel approach towards diabetes telecare", Med. Inform., Vol. 21, No. 4, 283-295, (1996)	

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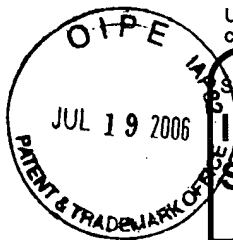
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	SS	TRAJANOSKI, ZLATKO, et al.: "Neural Predictive Controller for Insulin Delivery Using the Subcutaneous Route", IEEE Transactions on Biomedical Engineering, Vol. 45, No. 9, September (1998)	
	TT	BERGER, M.P.: "Combining Statistical, Rule-Based, and Physiologic Model-Based Methods to Assist in the Management...", Computer and Biomedical Research, Vol. 23, 346-357, (1990)	
	UU	FISHER, MICHAEL: "A Semiclosed-Loop Algorithm for the Control of Blood Glucose Levels in Diabetics", IEEE Transactions on Biomedical Engineering", Vol. 38, No. 1, January 1991	
	VV	HERNANDO, M.E. et al.: "DIABNET, a qualitative model-based advisory system for therapy planning in gestational diabetes", Med. Inform. Vol. 21, No. 4, 359-374, (1996)	
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	XX	PARKER, ROBERT, et al.: "Control-relevant modeling in drug delivery", Advanced Drug Delivery Reviews, Vol. 48, 211-228, (2001)	
	YY	CARSON, E.R., et al.: "Computers in Diabetes - an Introduction", Computer Meth Prg. Biomed., Vol. 62, 153-155, (2000)	
	ZZ	HAUSER, THOMAS, et al.: "Assessment of Experts' Approach to Insulin Therapy...", Diabetes Care, Vol. 15, No. 2, pp 221-, February (1992)	
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	bbb	SANDHAM, W.A., et al.: "Neural Network and Neuro-Fuzzy Systems for Improving Diabetes Therapy", Proceedings of the 20th Annual International Conference of the IEEE Engineering in Medicine and Biology Society, Vol. 20, No. 3, part 3/6, p 1438-1441(1998)	
	ccc	PARKER, R.S. et al: "Time and Frequency Domain Analysis of Blood Glucose Regulation Algorithms", Proceedings- 19th International Conference- IEEE/EMBS, Chicago, IL, Oct. 30- Nov. 2, (1997)	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 6 of 9

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Application Number	10/524,094
Filing Date	2/9/2005
First Named Inventor	Boris P. Kovatchev, et al.
Group Art Unit	1652
Examiner Name	Unknown
Attorney Docket Number	00543-22

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	ddd	PARKER, ROBERT S., et al.: "The Intravenous Route to Blood Glucose Control", IEEE Engineering in Medicine and Biology, pp 65-, January (2001)	
	eee	PARKER, ROBERT S., et al.: "A Model-Based Algorithm for Blood Glucose Control in Type 1 Diabetic Patients", IEEE Transactions on Biomedical Engineering, Vol. 46, No. 2, pp 148-, February (1998)	
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	ggg	KAN, SHUGEN, et al.: "Novel Control System for Blood Glucose Using a Model Predictive Method", ASAIO Journal, pp 657 - , (2000)	
	hhh	CANDAS, B.et al.: "An Adaptive Plasma Glucose Controller Based on a Nonlinear Insulin/Glucose Model", IEEE Transactions on Biomedical Engineering, Vol. 41, No. 2, pp 116 -, February (1994)	
	iii	ROBINSON, DAVID, et al.: "Knowledge of Diabetes mellitus and glycaemic control", Med. Principles Pract. Vol. 6, 186-197 (1997)	
	jjj	TOTH, MICHAEL, et al.: "Determinants of insulin-stimulated glucose disposal in middle-aged, premenopausal women", Am J Physiol Endocrinol Metab., Vol. 281, E113-E121, (2001)	
	kkk	BANDO, YUKIHIRO, et al.: "The Relationship of Fasting Plasma Glucose Values and Other Variables to 2-h-...", Diabetes Care, Vol. 24, No. 7, pp 1156 - , July (2001)	
	lll	LISZKA-HACKZELL, JAN JOHN.; "Prediction of Blood Glucose Levels in Diabetic Patients Using a Hybrid AI Technique", Computers and Biomedical Research, Vol. 32, 132-144 (1999)	
	m3	WALDHAUSL, WERNER, et al.: "Blood Glucose Response to Stress Hormone Exposure in Healthy Man...", IEEE Transactions on Biomedical Engineering, Vol. 39, No. 8, August (1992)	
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		Group Art Unit	1652
		Examiner Name	Unknown
Sheet 7 of 9	Attorney Docket Number	00543-22	

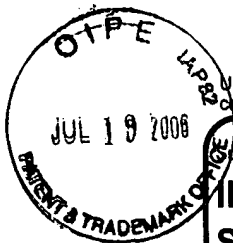
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	ooo	BASU, TK.; "Computer Simulation of Blood Glucose Level in Stress Conditions", pp 491 ABSTRACT ONLY	
	ppp	TRESP, Volker, et al.: "Neural-Network Models for the Blood Glucose Metabolism of a Diabetic", IEEE Transactions on Neural Networks, Vol. 10, No. 5, pp 1204-1213, September (1999)	
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	sss	CAVAN, D.A., et al.: "Use of the DIAS model to predict unrecognised hypoglycaemia in patients with insulin-dependent diabetes", Computer Methods and Programs in Biomedicine, Vol. 50, 241-246, (1996)	
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	vvv	CAVAN, DA, et al.: "Preliminary experience of the DIAS computer model in providing insulin dose advice to patients with insulin dependent diabetes", Computer Methods and programs in Biomedicine, Vol. 56, p 157-164, (1998)	
	w3	ANDREASSEN, STEEN, et al.: "A probabilistic approach to glucose prediction and insulin dose adjustment; description of metabolic model and pilot evaluation study", Computer Methods and Programs in Biomedicine, Vol. 41, 153-165, (1994)	
	xxx	TUDOR, ROMULUS, et al.: "DIAS-NIDDM- a model-based decision support system for insulin dose adjustment in insulin-treated subjects with NIDDM", Computer Methods and Programs in Biomedicine, Vol. 56, 175-192, (1998)	
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	zzz	BREMER, TROY, et al.: "Is Blood Glucose Predictable from Previous Values? A solicitation for data", Diabetes, Vol. 48, pp 445-451, March (1999)	
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	V	DCCT RESEARCH GROUP: "The effect of intensive treatment of diabetes on the development and progression of Long-term complications of insulin-dependent diabetes Mellitus", New England Journal of Medicine, Vol. 329, 977-986 (1993)	
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	VIII	DCCT RESEARCH GROUP: "Epidemiology of Severe Hypoglycemia In the diabetes control and complications trial", Amer. J. of Med., Vo. 90, 450-459, (1991)	
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	X	CRYER, PE: "Hypoglycemia is the limiting factor in the management of Diabetes", Diabetes Metab Res Rev, Vol. 15, 42-46, (1999)	

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	XI	SVENDSON, AABY, et al.: "Glycosylated Hemoglobin and Steady-State Mean Blood Glucose Concentration in Type 1 (Insulin-Dependent) Diabetes", Diabetologia, Vol. 23, 403-405, (1982)	
	XII	SANTIAGO, J.V.: "Lessons from the Diabetes Control and Complications Trial", Diabetes, Vol. 42, 1549-1554, (1993)	
	XIII	BOLLI, G.B.: "How to Ameliorate the Problem of Hypoglycemia in Intensive as well as Nonintensive Treatment of Type 1 Diabetes", Diabetes Care, Vol. 22, Supplement 2, B43-B52, (1999)	
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